No. 14-55633

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TODD SCHUENEMAN, on behalf of himself and all others similarly situated,

Plaintiff-Appellant,

v.

ARENA PHARMACEUTICALS, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of California
Hon. Cathy Ann Bencivengo
No. 3:10-cv-01959-CAB-BLM

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INTRODUCTION

This is a class action lawsuit against Arena Pharmaceuticals, Inc. ("Arena" or the "Company") and several of its executives (collectively "Defendants") alleging securities fraud. Arena is a pharmaceutical research and development company whose main product throughout the proposed class period ("Class Period") was a new weight management drug called lorcaserin. In 2009, Arena filed an application with the Food and Drug Administration ("FDA") seeking approval of lorcaserin (the "Lorcaserin Application").

In September of 2010, the FDA released a document regarding its assessment of lorcaserin (the "Briefing Document") revealing that the drug caused significant cancers in rats. Those findings were the result of a study performed by Defendants from 2006 through January of 2009 (the "Rat Study"). It is undisputed that Defendants knew about the negative results of the Rat Study and the FDA's serious concerns about their relevance to humans *for years*. It is also undisputed that Defendants *never* publicly disclosed that information even though they unfailingly promoted other positive test results and linked them to FDA approval.

Upon release of the Briefing Document, Arena's share price plummeted by approximately 40 percent. Days later, a panel of FDA scientists recommended against approval of the Lorcaserin Application, and Arena's stock price fell another 47 percent. This lawsuit followed.

Plaintiff's theory of fraud is straightforward. Defendants engaged in a multi-year campaign of omissions and misleading statements intended to completely suppress negative results of the Rat Study and the serious concerns repeatedly voiced by the FDA about those results. The motivation was to prevent investors from performing their own assessment of whether and when lorcaserin was likely to be approved. Defendants' deception propped up the value of Arena stock and enabled the Company to raise over $150 million in sorely needed capital. In short, this was a classic fraud on the market perpetrated for classic reasons.

The district court agreed that Defendants made material omissions and misrepresentations. The district court disagreed, however, that Plaintiff's allegations give rise to a "strong inference of scienter" (*i.e.*, the intent to mislead or deliberately reckless disregard for the fact that investors would be misled). Specifically, the district court held that Defendants' omissions and statements were more likely the result of a bona fide scientific disagreement with the FDA than the result of any intent to mislead. With respect, the district court was deeply confused.

Plaintiff's theory of fraud is not that Defendants intentionally misled the market about the safety of lorcaserin. Plaintiff's theory of fraud is that Defendants knew that the negative results of the Rat Study seriously concerned the FDA, and that by failing to disclose those facts, Defendants intentionally deprived the market of material information about whether and when the FDA would likely approve the

drug. That distinction is critical because even a perfectly safe drug cannot be sold until its safety has been demonstrated *to the FDA's satisfaction*. And the value of Arena's stock depended largely on investors' perceptions regarding that issue.

As explained in detail below, Plaintiff's allegations support a compelling inference of scienter. The district court's holding to the contrary is simply untenable. Indeed, if the overwhelming circumstantial evidence in this case of Defendants' intent to mislead is insufficient to avoid dismissal, then no securities plaintiff in the Ninth Circuit will ever obtain access to discovery except in the rare case where he already possesses *non-circumstantial* proof of the specific intent of executives (*i.e.*, admissions). That was not the goal of Congress in passing the Private Securities Litigation Reform Act ("PSLRA"). And it is irreconcilable with precedent interpreting the PSLRA's scienter requirement. Reversal is warranted.

STATEMENT OF THE ISSUES

1. The PSLRA requires a private securities plaintiff to plead facts giving rise to an inference of scienter that is at least as strong as any alternative inference. In ruling on a motion to dismiss for failure to adequately plead scienter, the reviewing court must accept the plaintiff's allegations as true and view them holistically. The first question presented by Appellant is this: did the district court err in dismissing the Second Amended Complaint on the grounds that its allegations do not give rise to a strong inference of scienter?

2. Dismissal without leave to amend is improper unless the pleading cannot possibly be cured. The second question presented by Appellant is this: did the district court err in denying Plaintiff leave to amend the Second Amended Complaint on the grounds that amendment would be futile?

JURISDICTIONAL STATEMENT

This action arises under 28 U.S.C § 1331 and Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78aa. Specifically, Lead Plaintiff Carl Schwartz ("Plaintiff" or "Appellant") alleges in the Second Consolidated Amended Class Action Complaint (the "Second Amended Complaint") and in the Proposed Third Consolidated Amended Class Action Complaint (the "Proposed Third Amended Complaint") violations of Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and 15 U.S.C. § 78t(a), and the rules and regulations promulgated thereunder by the U.S. Securities and Exchange Commission ("SEC"), including Rule 10b-5, 17 C.F.R. § 240.10b-5.

This Court has appellate jurisdiction under 28 U.S.C. § 1291 because this is an appeal from a final order, dated March 20, 2014, from the United States District Court for the Southern District of California that disposed of all claims in the proceedings below ("March 20 Order").[1] The District Court entered Final Judgment

[1] ER-1. "ER-__" refers to Appellant's Excerpts of Record.

dismissing the action with prejudice on March 21, 2014.[2] Pursuant to Fed. R. App. P. 4(a), Appellant timely filed his Notice of Appeal on April 18, 2014.[3]

STATEMENT OF THE CASE

I. Statutory Background

In the aftermath of the stock market crash of 1929, Congress enacted the Securities Act of 1933, 15 U.S.C. §§ 77a *et seq.*, and the Exchange Act to bolster investor confidence in the markets.[4] Among other provisions, the Exchange Act created a private right of action for defrauded purchasers and sellers of securities.[5] Plaintiffs were required to prove scienter: "a mental state embracing intent to deceive, manipulate, or defraud."[6]

In 1995, Congress reaffirmed the importance of private securities litigation as a tool for defrauded investors to recover their losses in enacting the PSLRA. As the House Conference Report explains:

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[2] ER-37.

[3] ER-32.

[4] *See, e.g.*, H.R. REP. NO. 104-369, at 31 (1995) (Conf. Rep.), *available at* http://www.gpo.gov/fdsys/pkg/CRPT-104hrpt369/pdf/CRPT-104hrpt369.pdf ("The overriding purpose of our Nation's securities laws is to protect investors and to maintain confidence in the securities markets . . . .").

[5] *See Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 196 (1976). This model incentivizes individuals to investigate and litigate fraud cases that the SEC may not bring. Bryant Garth et al., *The Institution of the Private Attorney General: Perspectives from an Empirical Study of Class Action Litigation*, 61 S. CAL. L. REV. 353, 360–66 (1988).

[6] *Hochfelder*, 425 U.S. at 192, 193 n.12.

> Private securities litigation is an indispensable tool with which defrauded investors can recover their losses without having to rely upon government action. Such private lawsuits promote public and global confidence in our capital markets and help to deter wrongdoing and to guarantee that corporate officers, auditors, directors, lawyers and others properly perform their jobs. This legislation seeks to return the securities litigation system to that high standard.[7]

To that end, the PSLRA imposed procedural hurdles to obtaining discovery in securities class actions.[8] And one provision created a heightened pleading standard for scienter requiring plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."[9]

The Supreme Court has since made clear that to effectuate Congressional intent, this "strong inference" requirement must be interpreted and applied in a way that "preserv[es] investors' ability to recover on meritorious claims."[10] Accordingly, "[t]he inference that the defendant acted with scienter need not be irrefutable, *i.e.* of the 'smoking-gun' genre, or even the 'most plausible of competing inferences.'"[11] A complaint meets the scienter standard whenever "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."[12]

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[7] H.R. REP. NO. 104-369, at 31.

[8] *See, e.g.*, 15 U.S.C. § 78u-4(b)(3)(B) (staying discovery pending any motion to dismiss).

[9] 15 U.S.C. § 78u-4(b)(2).

[10] *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

[11] *Id.* at 324.

[12] *Id.*

II. Factual Background

Defendants are Arena, a pharmaceutical research and development company, and its executives. They include the Company's President and Chief Executive Officer, Jack Lief ("Lief"); Senior Vice President and Chief Scientific Officer, Dominic P. Behan ("Behan"); Senior Vice President and Chief Medical Officer, William R. Shanahan ("Shanahan"); and former Vice President of Clinical Development, Christen "Christy" Anderson ("Anderson").[13]

Defendants developed the weight management drug lorcaserin and shepherded it through the late-stage animal and human testing necessary for FDA approval. The clinical studies on humans went well, but it became clear early in a mandatory long-term animal carcinogenicity study that lorcaserin causes cancer in rats. The FDA required Defendants to prolong the Rat Study to determine whether the carcinogenic mechanism only affects rats, and it requested bimonthly updates.

When Defendants finished the Rat Study in early 2009, they did not publicly announce the results. But they did fire 31 percent of their employees and order other cost-cutting measures. Within fourteen months, they raised over $150 million through stock issuances and secured a $100 million loan with a four-year term. By

[13] Chief Financial Officer Robert E. Hoffman ("Hoffman") was also named as a defendant in the Second Amended Complaint. ER-109 (SAC ¶ 2). To aid the Court, record cites to a specific paragraph of the Second or Proposed Third Amended Complaints are indicated by a parenthetical and, respectively, use the format "SAC ¶ __" and "TAC ¶ __".

the time the FDA rejected the Lorcaserin Application in late 2010, Defendants had acquired enough capital to fund their business through 2012.

Throughout this period, Defendants led the market to believe that FDA approval of lorcaserin would be seamless because the late-stage clinical and nonclinical testing was uniformly encouraging. They promoted the findings of the human studies and represented that those findings satisfied the FDA's safety concerns. Defendants never disclosed either the carcinogenicity data from the Rat Study or the FDA's concerns that those results were germane to humans. When FDA scientists released a Briefing Document describing the results of the Rat Study in September 2010, investors and analysts were shocked, and Arena's stock price collapsed. This lawsuit followed shortly thereafter.

Over the next few years, the parties disputed the sufficiency of Plaintiff's complaints. Plaintiff amended twice and submitted a Proposed Third Amended Complaint, and Defendants argued upon each revision that Plaintiff had failed to sufficiently allege scienter. The district court agreed every time. After granting two motions to dismiss, it concluded that further amendments would be futile because Plaintiff could not plead facts supporting the "strong inference" of scienter necessary to withstand a motion to dismiss. Because this Court reviews the dismissal of Plaintiff's complaint *de novo*, this brief rehearses the key facts.[14]

[14] *See infra* pages 9–24.

A. Defendants Conduct the Lorcaserin Human Studies.

Defendants conducted two major late-stage clinical trials of lorcaserin: (1) behavioral modification and lorcaserin for overweight and obesity management ("BLOOM"), and (2) behavioral modification and lorcaserin second study for obesity management ("BLOSSOM").[15] Both BLOOM and BLOSSOM assessed the cardiovascular safety of lorcaserin,[16] which was important to the FDA because the similar diet drug Phen-Fen had been removed from the market after it was shown to cause heart-valve disease.[17] The results of both BLOOM and BLOSSOM indicated that lorcaserin did not increase cardiovascular risk.[18]

B. Defendants Conduct the Lorcaserin Rat Study.

While the clinical trials were ongoing, Defendants conducted the Rat Study, a long-term nonclinical carcinogenicity study required for FDA approval.[19] Such studies are designed to detect the risk that humans will develop cancer as a result of

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[15] ER-121 (SAC ¶ 63).

[16] ER-136–37 (SAC ¶ 130) (quoting ER-234) (March 17, 2008 press release). Whenever the Second Amended Complaint quotes or cites press releases, SEC filings, or investor conference calls, the location of the original document in the record will be indicated.

[17] ER-121 (SAC ¶ 66); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release).

[18] ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release); ER-152–53 (SAC ¶ 198) (quoting ER-276) (November 9, 2009 press release).

[19] ER-120–22 (SAC ¶¶ 62, 63, 69).

lifetime use of the new drug.[20] If the drug causes cancer in rats, its sponsor must demonstrate that the carcinogenic mechanism is not relevant to humans.[21]

As of February 2007, the results of the Rat Study ("Initial Results") indicated that lorcaserin causes mammary tumors, brain cancer, skin cancer, and cancer in the connective tissue around nerves in rats.[22] The incidence of malignant mammary tumors was troubling because lorcaserin would be marketed to overweight women, who are at a higher risk for breast cancer, and the incidence of brain cancer was troubling because lorcaserin targets the central nervous system.[23]

On May 31, 2007, Defendants reported the Initial Results of the Rat Study to the FDA.[24] Defendants hypothesized that the Initial Results were irrelevant to humans because the carcinogenic mechanism was related to prolactin, a hormone only linked to cancer in rats (the "Prolactin Hypothesis").[25]

The FDA had serious concerns. It required Defendants to conduct further studies to substantiate the Prolactin Hypothesis (the "Follow Up Tests"),[26] and it took

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[20] ER-122 (SAC ¶ 69).
[21] ER-122 (SAC ¶ 70).
[22] ER-111 (SAC ¶ 12); ER-122 (SAC ¶ 72).
[23] ER-111 (SAC ¶ 12); ER-123 (SAC ¶ 73).
[24] ER-112 (SAC ¶ 15); ER-123 (SAC ¶ 75).
[25] ER-3.
[26] ER-3. Defendants hoped to show in the Follow Up Tests that lorcaserin causes a significant increase in prolactin production, which has been independently linked to cancer in rats. ER-4.

the highly unusual step of directing Defendants to prepare bimonthly updates on the results of the Follow Up Tests.[27] Defendants submitted bimonthly updates to the FDA throughout 2007 and 2008.[28]

Defendants' March 2008 bimonthly update reported that the incidence and proportion of female rats with cancerous tumors had increased at all doses.[29] The FDA requested a meeting with Defendants the next month to discuss the negative results of the Rat Study and their implications for humans, including for participants in the ongoing clinical trials.[30] At that April 9, 2008 meeting, the FDA conditionally permitted Defendants to continue clinical studies but requested a draft report of the final results of the Rat Study as soon as it was available.[31]

On February 3, 2009, Defendants submitted a draft report of the final results of the Rat Study to the FDA.[32] Consistent with the Initial Results, the report stated that lorcaserin had caused mammary tumors in rats at all doses, and that it had also caused brain and other cancers in rats.[33] With respect to the Follow Up Tests, the report disclosed that lorcaserin had no effect on prolactin in female rats and in fact

[27] ER-112 (SAC ¶ 15–16); ER-123–24 (SAC ¶¶ 75–79).
[28] ER-113–14 (SAC ¶¶ 19, 23, 25).
[29] ER-113 (SAC ¶ 20); ER-124 (SAC ¶ 83).
[30] ER-113 (SAC ¶ 21); ER-124 (SAC ¶ 83).
[31] ER-125 (SAC ¶ 88).
[32] ER-126 (SAC ¶ 93).
[33] ER-127 (SAC ¶ 100–01).

reduced prolactin in males by 50 percent.[34] The report concluded that lorcaserin did not cause the sustained and robust increase in prolactin that had been observed of drugs that do not cause cancer in humans.[35]

C. Defendants Promote Seamless FDA Approval of Lorcaserin Based on Results of the Human *and* Animal Studies.

It is undisputed that Defendants knew about the Rat Study and the FDA's serious concerns that its results were relevant to humans *for years* yet never publicly disclosed that information. At the same time, Defendants consistently disclosed positive results of the human trials in detail. And when Defendants mentioned the animal studies, they characterized them as categorically positive.

1. Defendants promote BLOOM and BLOSSOM findings and link them to the likelihood of regulatory approval.

Defendants consistently disclosed the positive cardiovascular data from BLOOM and BLOSSOM. For example, a March 30, 2009 press release described positive BLOOM results in painstaking detail:

> Lorcaserin was generally very well tolerated. The most frequent adverse events reported in Year 1 and their rates for lorcaserin and placebo patients, respectively, were as follows: [percentages for headache, upper respiratory tract infection, nasopharyngitis, sinusitis, and nausea]. The most frequent adverse events reported in Year 2 and their rates for lorcaserin and placebo patients, respectively, were as follows: [percentages for upper respiratory tract infection, nasopharyngitis, sinusitis, arthralgia, and influenza].

[34] ER-63 (TAC ¶ 67).
[35] ER-4.

> Adverse events of depression, anxiety and suicidal ideation were infrequent and reported at a similar rate in each treatment group, and no seizures were reported. Serious adverse events occurred with similar frequency in each group throughout the trial without apparent relationship to lorcaserin. One death occurred during the trial, which was a patient in the placebo arm.[36]

Similar representations were made in May and September of 2009.[37] In contrast, Defendants never disclosed the existence of the Rat Study at all.

Defendants also praised the *overall safety profile* of their drug in connection with these disclosures. For example, the day Defendants issued the press release quoted above, Defendant Shanahan represented, "[W]e're getting support for the excellent safety profile of the drug."[38] Defendant Lief also represented, "I'm really happy that we have such a safe drug without the CNS or cardiovascular side effects that have plagued other drugs potentially in the past."[39] During another conference call coinciding with the release of clinical data, Defendant Lief represented, "We think that this tolerability profile will provide physicians with the confidence to use lorcaserin as a first line therapy for the majority of their patients."[40]

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[36] ER-142 (SAC ¶ 153) (quoting ER-243–44) (March 30, 2009 press release).

[37] ER-145 (SAC ¶ 166) (quoting ER-54) (May 11, 2009 call); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release).

[38] ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call).

[39] ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call).

[40] ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call).

And Defendants touted the "excellent safety and tolerability profile" of lorcaserin—using that exact phrase four times on September 18, 2009 alone, the day they first reported that the integrated data from BLOOM and BLOSSOM ruled out the risk of valvulopathy.[41] Defendants never qualified their representations about the "excellent safety profile" of lorcaserin by disclosing the negative results of the Rat Study or the FDA's concerns about their relevance to humans.

On the contrary, Defendants explicitly linked the positive cardiovascular results of BLOOM and BLOSSOM, and the resulting safety profile, to the *FDA's safety concerns* with lorcaserin. These statements were calculated to confirm investors' preconceptions that the FDA's concern with lorcaserin was largely cardiovascular—the problem that caused the FDA to withdraw Fen-Phen from the market.[42] As Defendant Lief told investors:

> Based on results from the BLOOM trial meeting the FDA's efficacy criteria, and coupled with a strong tolerability profile, that includes no signal of FDA Valvulopathy at any time point over the two-year treatment period, *we believe that lorcaserin is approvable* for weight management, both here in the US, and eventually in Europe as well.[43]

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[41] ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release); ER-149–50 (SAC ¶ 186) (quoting ER-260–61, 263, 265–67) (September 18, 2009 call); ER–154 (SAC ¶ 205) (quoting ER-284) (November 10, 2009 call).

[42] ER-151 (SAC ¶ 188) (quoting ER-267–68) (September 18, 2009 call).

[43] ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call) (emphasis added).

Defendants drew the same connection for investors later that year, announcing that BLOOM and BLOSSOM data "rules out a risk of valvulopathy in lorcaserin patients *according to criteria requested by the FDA.*"[44] And Defendant Anderson represented, "I'll just reiterate that we did rule out the risk of valvulopathy *the way we agreed to with the FDA*. And I think this . . . supports the safety of the drug."[45]

2. Defendants fail to disclose the FDA's concerns and represent that there are no safety hurdles to approval.

As noted above, Defendants never publicly disclosed the Initial Results of the Rat Study, the FDA's reaction, or the existence of the Follow Up Tests. Instead, Defendants affirmatively represented that such data did not exist. For example:

Defendants made unqualified positive statements about the status of the animal studies of lorcaserin. Defendant Lief represented on a March 12, 2009 conference call, "[Our] confidence is based on the Phase II data, the Phase I data, the preclinical studies that was [sic] done, *all the animal studies that have been completed*, as well as how the studies are recruiting, have recruited, the retention in

[44] ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release) (emphasis added). Tellingly, Defendants consistently referred to heart valve disease as "FDA valvulopathy" or "FDA-defined valvulopathy." ER-144 (SAC ¶ 160) (quoting ER-315) (March 31, 2009 press release); ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call); ER-152–53 (SAC ¶ 198) (quoting ER-276) (November 9, 2009 press release).

[45] ER-151 (SAC ¶ 188) (quoting ER-267–68) (September 18, 2009 call) (emphasis added).

those studies, and that sort of thing."[46] Defendants' public filings with the SEC as of May 2009 likewise represented that "the long-term safety and efficacy" of lorcaserin had been "demonstrated," in part through "long-term preclinical toxicity *and carcinogenicity* studies. These preclinical, *animal studies* are required to help us and regulatory authorities assess the potential risk that drug candidates may be toxic or cause cancer in humans."[47]

Defendants made additional representations that other studies were uniformly encouraging. For example, Defendant Shanahan represented in a March 30, 2009 conference call, "[B]ased on *earlier data* and Lorcaserin-selected mechanism, the topline data has not indicated any significant safety concerns."[48] On the same call, Defendant Lief promised, "And you will see *when the full data set* is presented, our drug will be very safe, well-tolerated."[49] And on September 18, 2009, Defendant Lief emphasized that "the [hypothalamic] mechanism is very consistent with the

[46] ER-139–40 (SAC ¶ 144) (quoting ER-387–88) (March 12, 2009 call) (emphasis added).

[47] ER-153 (SAC ¶ 200) (quoting ER-351–52, 359) (Third Quarter 2009 Form 10-Q) (emphasis added).

[48] ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call) (emphasis added).

[49] ER-143 (SAC ¶ 157) (quoting ER-310–11) (March 30, 2009 call) (emphasis added).

clinical *as well as pre-clinical* experience that we know for lorcaserin" and stated that lorcaserin is "a very effective drug, very safe."[50]

Finally, Defendants repeatedly represented that the positive results they had disclosed constituted the complete data set accompanying the Lorcaserin Application. On three separate calls between August and November 2009, Defendants represented that they had completed their research:

- August 3, 2009: "The (inaudible) study pretty much finished up that package that we are planning to submit to the FDA as our initial [Lorcaserin Application], so we will have no additional studies that we will be submitting in the initial [Lorcaserin Application] once we complete that study report."[51]

- September 18, 2009: "You know, we've, I think put together pretty much all of the data that we now need for this [Lorcaserin Application]. *We have favorable results on everything that we've compiled so far***.**"[52]

- November 10, 2009: "I am pleased to report at this time we have all of the data in hand that will be included in the new drug application that we are planning to submit to the FDA next month."[53]

Defendants' statements led investors to believe that Defendants had not only completed their research, but also *disclosed* all the material data to be included in

[50] ER-149–50 (SAC ¶ 186) (quoting ER-260–61, 263, 265–67) (September 18, 2009 call) (emphasis added).

[51] ER-147 (SAC ¶ 175) (quoting ER-368) (August 3, 2009 call) (response to analyst question, "Are there any other gating studies, preclinical or clinical, that are still needed at the FDA?").

[52] ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call) (emphasis added).

[53] ER-154 (SAC ¶ 204) (quoting ER-282, 284) (November 10, 2009 call).

the Lorcaserin Application. For example, in the September 18, 2009 call, Defendant Behan said, "*As you can see from the data*, we believe that lorcaserin is a game changer."[54] At a minimum, these statements falsely suggested that there were no undisclosed *negative* results to be submitted to the FDA.[55]

D. Defendants Reduce Operating Expenses and Procure Capital.

In January 2009, as the Follow Up Tests concluded, Arena directed its purchasing department to suspend all future purchases unless absolutely necessary.[56] Three months later, Arena announced plans to fire 31 percent of its workforce.[57] All told, Arena reduced its administrative costs by $5 million in 2009 after multi-million dollar *increases* in each of the two previous years.[58] Arena employees understood that these measures were related to uncertainty as to whether lorcaserin would make it to market and, if so, when.[59]

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[54] ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call) (emphasis added).

[55] ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call); ER-206 (SAC ¶ 206) (quoting ER-286) (November 10, 2009 call) ("[A]t the present time, we don't see safety signal [sic] to pursue, so we are going to down [sic] evaluate our data, file the [Lorcaserin Application] and then have discussions with the FDA after that.").

[56] ER-114 (SAC ¶ 27).

[57] ER-438 (First Quarter 2009 Form 10-Q).

[58] *See* Arena's Annual Fiscal Year 2009 Form 10-K, at 47, available at http://www.sec.gov/edgar.shtml.

[59] For example, a Purchasing Manager learned that the suspension of future purchases was due to uncertainty about regulatory approval of lorcaserin. ER-62 (SAC ¶¶ 62–63). Another employee heard that the layoffs were likely linked to

While Arena was implementing cost-cutting measures, it was also fundraising. Arena raised over $150 million through stock issuances from April 2009 to June 2010 alone.[60] By comparison, Arena issued under $2 million worth of new stock in all of 2008.[61] In addition, on July 6, 2009, Arena secured a $100 million loan from Deerfield.[62] The loan had a four-year term, with a balloon payment of $40 million plus interest due at the end of the term.[63] Arena raised $190 million in total,[64] or enough to fund its operations through 2012.[65]

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management's concerns about the future of lorcaserin. ER-114–15 (SAC ¶¶ 27, 29); ER-63–63 (SAC ¶ 72).

[60] ER-120 (SAC ¶ 60); ER-126 (SAC ¶ 95); ER-127 (SAC ¶ 103); ER- 129 (SAC ¶ 112).

[61] Gurufocus, *Arena Pharmaceuticals Inc (NAS:ARNA) Net Issuance of Stock*, (last visited August 27, 2014), http://www.gurufocus.com/term/Net%20Issuance%20of%20Stock/ARNA/Net%252BIssuance%252Bof%252BStock/Arena%2BPharmaceuticals%252C%2BInc.

[62] ER-222 (Annual Fiscal Year 2009 Form 10-K).

[63] ER-222 (Annual Fiscal Year 2009 Form 10-K).

[64] 150 million is the sum of Arena's stock issuances and the last $40 million of the Deerfield loan, which Arena did not have to pay back until 2013. ER-222 (Annual Fiscal Year 2009 Form 10-K).

[65] *See generally* Arena's First, Second, and Third Quarter 2012 Form 10-Qs, and Annual Fiscal Year 2012 Form 10-K, available at http://www.sec.gov/edgar.shtml. If this Court (like the district court) decides to consider events which occurred *after* the Class Period, such as the 2012 FDA approval of lorcaserin, it must examine those events in context. That would require consideration of the information described in this footnote and the accompanying text.

E. Defendants File the Lorcaserin Application with the FDA.

On December 18, 2009, Defendants submitted the Lorcaserin Application to the FDA.[66] The Lorcaserin Application included both the Initial Results of the Rat Study and the results of the Follow Up Tests, as well as the results of other nonclinical and clinical studies.[67] The Lorcaserin Application stated that the Follow Up Tests found, among other things, that "malignant mammary tumors were primarily prolactin negative."[68] To put it mildly, the Follow-Up Tests failed to conclusively support the Prolactin Hypothesis.

Nonetheless, Defendants continued to promote aggressively the data they had presented to the FDA without ever disclosing the negative results of the Rat Study or the FDA's concerns that the results were relevant to humans. A few days after submitting the Lorcaserin Application, Defendants issued a press release touting "the robust data package we submitted to the FDA" and specifically describing the results of BLOOM and BLOSSOM.[69] And a press release issued two months later presented the results of the clinical trials in even greater detail again touting the "excellent safety" of lorcaserin.[70]

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[66] ER-115 (SAC ¶ 30).
[67] ER-115 (SAC ¶ 30).
[68] ER-124 (SAC ¶ 79).
[69] ER-155 (SAC ¶ 209) (quoting ER-231) (December 22, 2009 press release).
[70] ER-155 (SAC ¶ 211) (quoting ER-288) (February 24, 2010 press release).

Defendants also continued to represent that there was no undisclosed data that would impair the prospects of the Lorcaserin Application. In a March 12, 2010 conference call about the pending FDA review of the Lorcaserin Application, Defendant Lief told investors, "The FDA has said that there is sufficient data to review lorcaserin on its merits. We have also had discussions and meetings around that."[71] When asked whether the FDA had raised any questions or issues, Defendant Lief responded, "Well, we typically do not go into the details of FDA correspondence. Having said that, we are confident that we have the ability to work with the FDA in the future . . . ."[72] Defendant Lief said on the same call, "Lorcaserin was so well tolerated, and we don't see any safety signals that require special attention right now."[73]

During this period, Defendants retained an independent world-renowned pathologist to make a presentation about the Rat Study to the FDA's Endocrinology and Metabolic Advisory Committee ("Advisory Committee") at its meeting to consider whether to recommend lorcaserin for FDA approval, reflecting Defendants' knowledge that the Rat Study's negative results were of serious and continued concern to the FDA.[74] Defendants' pathologist was an expert in chemical

[71] ER-157 (SAC ¶ 219) (quoting ER-390, 392, 393) (March 12, 2010 call).
[72] ER-157–58 (SAC ¶ 221) (quoting ER-394) (March 12, 2010 call).
[73] ER-157–58 (SAC ¶ 221) (quoting ER-394) (March 12, 2010 call).
[74] ER-115 (SAC ¶ 32); ER-128 (SAC ¶ 108).

carcinogenesis in animals, and he worked with Defendants to prepare slides explaining the negative results of the Rat Study.[75] Yet when an analyst asked Defendants what they were focusing on in their preparations, Defendant Shanahan said, "we're not expecting any surprises associated with the panel," and Defendant Anderson added only, "Obviously, we've always said that the primary focus would be on safety, and we are well prepared to thoroughly address the safety issues, the safety data, as well as the efficacy data with the panel."[76] Again, Defendants did not disclose the negative results of the Rat Study or the FDA's concerns about their relevance to humans.

F. The FDA Discloses Results of the Rat Study, Investors Are Shocked, and Arena's Stock Price Collapses.

On September 14, 2010, the FDA released a Briefing Document for the Advisory Committee panel.[77] The Briefing Document publicly disclosed the negative results of the Rat Study and the FDA's serious concerns about them.[78]

Investors were shocked.[79] A Summer Street Analyst Report captured the prevailing sentiment: "Yesterday we were *completely blindsided* by preclinical

[75] ER-115 (SAC ¶ 32); ER-128 (SAC ¶ 108).
[76] ER-161–62 (SAC ¶ 240) (quoting ER-400) (August 3, 2010 call).
[77] ER-116 (SAC ¶ 36); ER-129 (SAC ¶ 114).
[78] ER-116 (SAC ¶ 36); ER-129 (SAC ¶ 114).
[79] ER-116 (SAC ¶ 37); ER-130 (SAC ¶ 116) (collecting statements).

carcinogenicity data from the two year lorcaserin animal study."[80] J.P. Morgan wrote similarly, "The biggest surprise is a preclinical cancer signal. We (and investors we've spoken with this morning) were caught off guard by the question relating to lorcaserin-related tumors in rats."[81]

Analysts uniformly cautioned that new information worsened the prospects for imminent FDA approval of lorcaserin. For example, Cowen told investors, "We believe the fact that the FDA believes that lorcaserin increases the risk for malignant breast tumors in rats reduces the likelihood that lorcaserin will receive a positive panel recommendation on Thursday."[82] Oppenheimer wrote similarly, "We see the FDA's rejection of [Defendants'] explanation of pre-clinical cancers in rats as a significant concern."[83] And Summer Street warned, "Most importantly, we do not believe Arena will be able to produce preclinical data and/or design a post-approval trial/registry to rule out a breast cancer risk."[84]

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[80] ER-130 (SAC ¶ 116) (quoting September 15, 2010 Summer Street Analyst Report) ("Summer Street Analyst Report") (emphasis added).

[81] ER-130 (SAC ¶ 116) (quoting September 14, 2010 J.P. Morgan *ALERT*) (emphasis removed); *see also* ER-130 (SAC ¶ 116) (quoting September 14, 2010 Jefferies Analyst Report) ("The biggest surprise in the briefing documents is the finding of preclinical cancers."); ER-130 (SAC ¶ 116) (quoting September 14, 2010 Cowen Analyst Report entitled "Quick Take: Rat Carcinogenicity Data A Surprise In Briefing Docs") ("Cowen Analyst Report").

[82] ER-130 (SAC ¶ 116) (quoting Cowen Analyst Report).

[83] ER-130 (SAC ¶ 116) (quoting September 14, 2010 Oppenheimer Analyst Report) (emphasis removed).

[84] ER-130 (SAC ¶ 116) (quoting Summer Street Analyst Report).

Investors agreed. Arena stock fell from $6.85 per share at the close of trading the day before to $4.13 per share at the close of trading on September 14, 2010—a one-day decline of 40 percent that wiped out millions of dollars of shareholder value.[85] Trading in Arena common stock was halted the next day.[86]

III. Procedural History

A few days later, Arena investors sued Defendants under Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5.[87] Following his appointment as Lead Plaintiff, Plaintiff filed an amended complaint ("First Amended Complaint"), setting forth facts gleaned from publicly available information and interviews with confidential informants in support of his claim that Defendants artificially inflated the price of Arena stock for over two years by misleading the market about the likelihood and timing of FDA approval of lorcaserin.[88]

The district court dismissed the First Amended Complaint without prejudice on two grounds related to scienter: first, that Plaintiff had not adequately alleged each Defendant's knowledge of the Rat Study and the FDA's concerns;[89] and second,

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[85] ER-116 (SAC ¶ 37); ER-129 (SAC ¶ 115).
[86] ER-116 (SAC ¶ 37).
[87] Complaint, Dkt. No. 1.
[88] First Amended Complaint, Dkt. No. 43.
[89] In so holding, the district court misapplied the core operations inference. After first noting, "Lorcaserin was Arena's core product. Defendants were focused on the development of lorcaserin, they discussed lorcaserin in every conference call, press release and periodic report filed by Arena with the SEC, and nearly all of the

that it was "more plausible that [Defendants] knew about the Rat Study data and reasonably believed the results to be *positive* with regard to what the study was designed to test"—whether lorcaserin causes cancer in humans—than that they recklessly disregarded the falsity of their statements.[90]

Plaintiff filed a Second Amended Complaint on May 13, 2013, adding facts to establish each Defendant's personal knowledge of the Rat Study results and the FDA's communications with Arena about them.[91] The district court then held a lengthy oral argument on Defendants' motion to dismiss the Second Amended Complaint.[92] During that hearing, the district court initially expressed skepticism about Defendants' position, noting for example that "the company was telling [investors] that they had favorable results on everything and, yet, the fact pattern doesn't seem to indicate that they were in a favorable position in 2009"[93] and that she was inclined "to deny the motion to dismiss based on at least the statements that were made in September of 2009."[94] But defense counsel steered the hearing toward

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Company's resources were dedicated to lorcaserin's development," the district court continued, "However, the facts presently before the Court do not warrant the application of the 'core operations' scienter theory . . . ." ER-28. The court's conclusion does not follow from its premises.

[90] ER-30 (emphasis added).

[91] ER-106–173.

[92] Transcript of Proceedings held on October 18, 2013, Dkt. No. 82, 6:16–18 ("October 2013 Hearing Transcript").

[93] October 2013 Hearing Transcript 6:16–18.

[94] October 2013 Hearing Transcript 7:4–6.

the scientific implications of the Follow Up Tests,[95] and the judge was led to view this case as a scientific dispute: "Their scientific interpretation of this has to be demonstrated to be wrong . . . ."[96]

On November 4, 2013, the district court entered an order ("November 4 Order") dismissing the Second Amended Complaint without prejudice, again on the grounds that it "fails to meet the Ninth Circuit's pleading requirements for scienter."[97] Specifically, the November 4 Order concluded that Defendant Lief's March 12, 2009 statement that "confidence is based on . . . the preclinical studies

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[95] October 2013 Hearing Transcript 14:4–11 ("It's the single most important factor in this case because the FDA . . . mechanistically combined all the data so that it could make a determination with independent pathologists what do these slides show. And when those independent pathologists reviewed the data, it agreed that the data was correct, and in fact, it was less cancer that Arena had suggested.").

[96] October 2013 Hearing Transcript at 37:12–14.

[97] ER-8. The November 4 Order also dismissed Defendant Hoffman from this action on the grounds that Plaintiff did not "sufficiently plead his knowledge of the Rat Study data." ER-12 (footnote 4). This Court should reverse that dismissal. As noted in *supra* note 89, the district court acknowledged that every public statement made by Arena during the Class Period discussed lorcaserin and nearly all of its resources "were dedicated to lorcaserin's development." ER-28. Under these circumstances, the results of the Rat Study were sufficiently prominent "that it would be 'absurd' to suggest that management was without knowledge of the matter." *South Ferry LP, # 2 v. Killinger*, 542 F.3d 776, 786 (9th Cir. 2008) (citing *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 988 (9th Cir. 2008)). In addition, Defendant Hoffman signed the Sarbanes-Oxley certifications that accompanied each regulatory disclosure. ER-138 (SAC ¶ 134). Thus, the Second Amended Complaint contains "specific allegations that [Defendant Hoffman] actually did monitor the data that were the subject of the allegedly false statements. That is sufficient under the PSLRA." *South Ferry*, 542 F.3d at 785 (citing *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022–23 (9th Cir. 2005)).

that was [sic] done, all the animal studies that have been completed" did not demonstrate recklessness because Defendants reasonably believed lorcaserin's overall safety profile and potential to be "positive, favorable, or encouraging."[98] The court also cited the fact that the FDA had "ultimately [*i.e.*, two years later] accepted and agreed with Arena's final data" as evidence of an absence of scienter.[99] Finally, the district court found that Defendant Anderson's September 18, 2009 statement, "We have favorable results on everything that we've compiled so far," *might* be misleading, but only if Plaintiff could "show this case to be about more than a difference of scientific opinion . . . ."[100]

The November 4 Order invited Plaintiff to amend with the instruction to "dramatically limit his amended complaint to . . . statements that support Plaintiff's theory that Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism . . . ."[101] For example, the court advised Plaintiff to remove statements limited to the BLOOM and BLOSSOM clinical trials,[102] and cautioned that the allegations relating to stock

[98] ER-14–15.
[99] ER-14–15.
[100] ER-15–16.
[101] ER-16 (footnote 9).
[102] ER-19 (footnote 13).

sales and budget cuts "do not meaningfully contribute to a strong inference of scienter with respect to the overall safety statements."[103]

On November 27, 2013, Plaintiff moved for leave to amend the Second Amended Complaint and attached the Proposed Third Amended Complaint, which followed the district court's instructions to the letter.[104] Nevertheless, the district court denied leave to amend on March 20, 2014 ("March 20 Order"), on the grounds that amendment would be futile because the Proposed Third Amended Complaint still did not adequately plead scienter.[105]

The March 20 Order focused on whether Plaintiff adequately alleged that Defendants intentionally misrepresented the safety of lorcaserin because they knew that the Follow Up Tests did not support the Prolactin Hypothesis.[106] The district court concluded that it was "more plausible" that Defendants had a legitimate scientific disagreement with the FDA about the implications of the Follow Up Tests.[107] The district court observed that Plaintiff did not allege that Defendants interpreted the Follow Up Tests unreasonably or that they did not actually believe that the Follow Up Tests supported the Prolactin Hypothesis.[108]

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[103] ER-15 (footnote 8).
[104] Motion to Amend, Dkt. No. 73; ER-43 (TAC).
[105] ER-8.
[106] ER-1–7.
[107] ER-6.
[108] ER-6–7.

With respect to Defendants' misrepresentations about the prospects for regulatory approval of lorcaserin, the district court acknowledged in passing that "Defendants may have known that there was a *theoretical risk* that the FDA would disagree" with their assessment of the Follow Up Tests, but emphasized that there were no facts "suggesting Defendants knew they had to show that lorcaserin caused a sustained and robust increase in prolactin to obtain FDA approval."[109] The district court focused on the absence of allegations that Defendants "were on notice that the FDA would opine that the [Follow Up Tests] failed to substantiate the Prolactin Hypothesis."[110] Somewhat amazingly, the court concluded that Defendants' scientific disagreement with the FDA was "unanticipated."[111]

On March 20, 2014, final judgment was entered. This appeal followed.

STANDARD OF REVIEW

Plaintiff seeks reversal of the November 4 Order dismissing the Second Amended Complaint and, in the alternative, the March 20 Order denying Plaintiff's motion for leave to amend. This Court reviews both orders *de novo*.[112]

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[109] ER-4–5 (emphasis added).
[110] ER-5.
[111] ER-6.
[112] *Whitman v. Mineta*, 541 F.3d 929, 931 (9th Cir. 2008); *Livid Holdings Ltd. v. Salomon Smith Barney*, 416 F.3d 940, 946 (9th Cir. 2005).

The question presented in a motion to dismiss is whether Plaintiff is entitled to offer evidence to support his claim, not whether Plaintiff will prevail.[113] In answering that question, the Court accepts Plaintiff's allegations as true and draws all reasonable inferences in Plaintiff's favor.[114] Even if the chance of recovery is remote, the Court allows Plaintiff to develop his case "unless the complaint fails to 'state a claim to relief that is plausible on its face.'"[115]

With respect to leave to amend, this Court has "repeatedly held that a district court should grant leave to amend . . . unless it determines that the pleading could not possibly be cured by the allegation of other facts."[116] Accordingly, dismissal with prejudice "is improper unless it is clear, upon *de novo* review, that the complaint could not be saved by any amendment."[117]

SUMMARY OF ARGUMENT

The district court fundamentally misunderstood Plaintiff's theory of fraud. In assessing scienter, it asked whether Plaintiff had adequately alleged that Defendants intentionally misled the market about the *safety* of lorcaserin, and it answered that

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[113] *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *overruled on other grounds by Davis v. Scherer*, 468 U.S. 183 (1984).

[114] *Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987).

[115] *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)); *United States v. City of Redwood City*, 640 F.2d 963, 966 (9th Cir. 1981).

[116] *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000).

[117] *Livid Holdings*, 416 F.3d at 946.

Defendants had a legitimate scientific disagreement with the FDA and thus lacked fraudulent intent. But Plaintiff's theory of fraud is that Defendants intentionally misled the market about whether and when the FDA would approve lorcaserin, not its actual safety. That is a critical difference. By depriving investors of the opportunity to independently evaluate how the FDA might act in light of the Rat Study and the FDA's repeatedly expressed concerns, Defendants committed fraud.

Without the benefit of formal discovery, Plaintiff has amassed substantial circumstantial evidence that Defendants intentionally perpetrated this fraud. The evidence shows that: (1) since the beginning of the Class Period, Defendants knew about the Rat Study's negative results and the FDA's concerns about their relevance to human risk; (2) Defendants selectively disclosed and withheld the results of late-stage testing depending on whether they were favorable to the prospects for FDA approval; (3) Defendants misrepresented these results to make FDA approval seem more likely and imminent; and (4) Defendants believed that FDA approval of lorcaserin would be delayed, if not denied altogether. In dismissing these allegations out of hand, the district court failed to read the Second Amended Complaint either holistically or in the light most favorable to Plaintiff.

The district court's application of the PSLRA's requirement that a plaintiff plead scienter was also far too stringent. Indeed, it appears that nothing short of direct evidence showing Defendants' intent to defraud the market would have

satisfied the district court. That is surely not a requirement Congress sought to impose when it enacted the PSLRA. And it is directly contradictory to the Supreme Court's admonition that the "strong inference" of scienter standard must be applied in a way that "preserv[es] investors' ability to recover on meritorious claims"[118] by "allow[ing] meritorious actions to go forward."[119]

ARGUMENT

I. The District Court Misapprehended Plaintiff's Theory of Fraud.

The district court erred when it dismissed the Second Amended Complaint and, for similar reasons, denied leave to amend the Second Amended Complaint as futile. The district court misapplied the scienter requirement because it erroneously believed that Defendants' scienter turned on subjective beliefs about lorcaserin's safety.[120] In fact, scienter turns on Defendants' objective awareness of the negative results of the Rat Study and the FDA's expressed concerns about those results.

A. Plaintiff's Theory of Fraud Is that Defendants Intentionally Misled Investors about Whether and When the FDA Was Likely to Approve Lorcaserin.

Defendants committed a classic fraud on the market for the classic reasons. According to the Second Amended Complaint, Defendants concealed the negative

[118] *Tellabs*, 551 U.S. at 322.

[119] *Id.* at 324.

[120] The court did correctly articulate the standard, which requires Plaintiff to plead facts giving rise to a strong inference that Defendants acted with scienter. ER-9.

results of the Rat Study and the FDA's concerns about their implications for humans with the intent to deprive the market of material information about the likelihood and timing of FDA approval. In this way, Defendants artificially inflated the price of Arena stock for months and raised over $150 million in capital for the Company. Plaintiff's theory of securities fraud proceeds in three steps.

1. Arena's stock price was based on investor perceptions about whether and when the FDA would approve lorcaserin.

During the Class Period, the business of Arena was focused primarily on lorcaserin.[121] For example, "[a]ccording to the 2009 10-K, approximately 95% and 86% of Arena's total external clinical and preclinical study fees and expenses related to lorcaserin in 2008 and 2009, respectively."[122]

Investor perceptions regarding the prospects of FDA approval of lorcaserin were, to put it mildly, a significant driver of Arena's stock price. Indeed, the price of Arena stock fluctuated dramatically upon any news that affected those

[121] ER-50–51 (SAC ¶ 50) (citing ER-212) (Fiscal Year 2009 Form 10-K).
[122] ER-50–51 (SAC ¶ 50) (citing ER-212) (Fiscal Year 2009 Form 10-K).

perceptions.[123] And it was not only the likelihood of lorcaserin's approval by the FDA that mattered to investors, but also the *expected timing* of that approval.[124]

The timing of FDA approval was crucial for two reasons. First, the longer Arena was expected to remain in the developmental period for lorcaserin, the more capital the Company would need to raise to remain solvent. The risk of insolvency was significant because pharmaceutical research and development companies consume capital at an astounding rate. Indeed, as Arena noted in 2009:

> We do not have any commercially available drugs, and we have substantially less money than we need to develop our compounds into marketed drugs. It takes many years and potentially hundreds of millions of dollars to successfully develop a preclinical or early clinical compound into a marketed drug, and our efforts may not result in any marketed drugs. . . . If adequate funding is not available, we will have to eliminate or further postpone or scale back some or all of our research or development programs or delay the advancement of one or more of such programs, including our lorcaserin program.[125]

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[123] *See, e.g.*, ER-116 (SAC ¶¶ 36–37); ER-129 (SAC ¶¶ 114–15); ER-165 (SAC ¶ 254) (Arena's share price declined approximately 40 percent upon release of the Briefing Document); ER-116 (SAC ¶¶ 38–39); ER-165 (SAC ¶ 256) (Arena's share price further declined approximately 47 percent upon vote of Advisory Committee).

[124] *See* ER-117 (SAC ¶¶ 43–44); ER-135 (SAC ¶¶ 127–28); ER-165 (SAC ¶ 257–58) (Arena's share price declined approximately 19 percent upon disclosure that FDA had recommended lorcaserin studies of at least 12 months). *See also* ER-117 (SAC ¶¶ 40–44); ER-134–35 (SAC ¶¶ 124–28) (decline in stock price was caused by frustration of widely-held expectation that further lorcaserin studies required by the FDA would be "short in duration").

[125] ER-436 (First Quarter 2009 Form 10-Q).

A prolonged approval process would also increase Arena's total expenses to develop lorcaserin without any offsetting increase in expected revenues, further decreasing the value of Arena stock.

Second, basic accounting principles dictate that dollars earned in the future are worth less than dollars earned today.[126] Thus, the more distant in the future Arena's projected revenues from selling lorcaserin became, the less Arena's stock was currently worth.

2. Investor perceptions about whether and when the FDA would approve lorcaserin turned on investor beliefs about how satisfied the FDA was with the safety of lorcaserin.

As the Second Amended Complaint explains, "a drug sponsor must demonstrate the drug's safety. Safety with respect to diet drugs was highly important because prior FDA-approved diet drugs, including Fen-Phen, were removed from the market because of serious adverse side effects . . . ."[127] It was particularly important for Defendants to demonstrate lorcaserin's lack of side effects because it affects the brain and central nervous system in similar ways as Fen-Phen.[128]

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[126] *See e.g.*, Investopedia, *Definition of Time Value of Money* (last visited August 26, 2014), http://www.investopedia.com/terms/t/timevalueofmoney.asp. *See also Donell v. Kowell*, 533 F.3d 762, 772 (9th Cir. 2008) (applying time value of money).

[127] ER-121 (SAC ¶ 65).

[128] ER-121 (SAC ¶ 66).

Defendants were keenly aware of this dynamic. "In February 2008, just before the beginning of the Class Period, Defendant Lief acknowledged that focus was on 'safety, safety, safety, safety . . . and then safety.'"[129] And Defendant Lief later reiterated, "We have always stated that safety is of paramount importance to the FDA, and that the right profile of efficacy, safety, and tolerability is essential for a weight-management drug."[130]

3. Defendants concealed the Rat Study's negative results and the FDA's concerns about them from the public in order to manipulate investor perceptions.

Plaintiff has alleged that Defendants knew that the negative results of the Rat Study and the FDA's expressed concerns about them would affect investor perceptions about the prospects for regulatory approval of lorcaserin, and thus would be material to their investing decisions.[131] Defendants engaged in a pattern of misrepresentations and omissions to conceal these facts.[132]

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[129] ER-121 (SAC ¶ 66).

[130] ER-161 (SAC ¶ 238) (quoting ER-398) (August 3, 2010 call).

[131] *No. 84 Employer-Teamster Joint Council Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 934 (9th Cir. 2003) ("[A] fact is material if there is a 'substantial likelihood' that a reasonable investor would consider it important in his or her decision making.").

[132] *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005) ("Whether Defendants had to predict the efficacy of [new drug] REMUNE is irrelevant. Defendants are liable under section 10(b) and rule 10b-5 if they made misstatements that a reasonable investor would consider in deciding whether to buy IRC's stock.").

The materiality of the negative results of the Rat Study and the FDA's concerns were apparent. The Rat Study was a prerequisite for FDA approval.[133] By February 2007, it showed that lorcaserin causes lethal breast, brain, skin and nerve-sheath tumors.[134] When Defendants reported these adverse results to the FDA,[135] the agency required Defendants "to warn humans participating in the lorcaserin clinical trials of the mammary and brain cancer risks that were observed in the Rat Study"[136] and to "provide bi-monthly updates to the FDA regarding the incidence of observed tumors in the Rat Study, including survival and tumor incidence."[137] As Defendant Lief later admitted, "Arena's bi-monthly updates to the FDA were highly unusual and not part of the normal process with the FDA."[138]

By the beginning of the Class Period, reasonable people in Defendants' position would have disclosed the results of the Rat Study and the FDA's expressed concern about the safety of lorcaserin. Reckless people would have said nothing, allowing investors to draw their own ill-informed conclusions. Defendants' conduct was more than reckless. *For over two years*, Defendants engaged in an affirmative pattern of false and misleading statements intended to suppress the negative results

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[133] ER-120–22 (SAC ¶¶ 62, 63, 69).
[134] ER-111 (SAC ¶ 12); ER-122 (SAC ¶ 72).
[135] ER-112 (SAC ¶ 15); ER-123 (SAC ¶ 75).
[136] ER-117 (SAC ¶ 41) (citing letters dated June 28, 2007 and August 29, 2007).
[137] ER-117 (SAC ¶ 47).
[138] ER-118 (SAC ¶ 48).

of the Rat Study and the serious concerns repeatedly expressed by the FDA. The most likely explanation: Defendants intended to prevent investors from performing their own assessment of whether and when lorcaserin might be approved.[139] Defendants succeeded, and investors lost.

Plaintiff's theory, that Defendants perpetrated an ordinary fraud by concealing material information about the likelihood of regulatory approval, is hardly novel. This Court recognized and approved that precise theory of relief in *Warshaw v. Xoma Corp.*[140] In *Warshaw*, this Court explained that the complaint sufficiently alleged that the defendant pharmaceutical company's representations about its new drug "were designed to prevent shareholder flight in the aftermath of a damaging report regarding the possible hazards of [the new drug] and the unlikelihood of FDA approval."[141] District courts followed suit in *In re Connetics Corp. Securities Litigation*,[142] *In re CV Therapeutics, Inc.*,[143] and *In re Immune Response Securities Litigation*.[144]

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[139] *See infra* pages 42–55 (Argument Section II).

[140] 74 F.3d 955, 959–60 (9th Cir. 1996).

[141] *Id.*

[142] No. C 07-02940 SI, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008).

[143] No. C 03-03709 SI, 2004 WL 1753241 (N.D. Cal. Aug. 5, 2004).

[144] 375 F. Supp. 2d 983. *See also In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 31 (D. Mass. 2004) (denying motion to dismiss where defendants failed to disclose adverse results of animal study in face of FDA concerns known to defendants).

In *Connetics*, for example, the defendant pharmaceutical company and its officers touted the progress of their new acne medication Velac but "failed to inform investors about the results of a pre-clinical test performed on transgenic mice [("Mouse Study") that] demonstrated that Velac caused 'cancerous skin tumors' in 89 out of approximately 160 mice."[145] Plaintiffs alleged that defendants' concealment of the negative results of the Mouse Study and the FDA's concerns about them for over a year misled the market about the prospects for FDA approval, and the district court denied defendants' motion to dismiss.[146]

Similarly, in *CV Therapeutics*, the district court denied a motion to dismiss allegations that a pharmaceutical company and its officers fraudulently failed to disclose their communications with the FDA about the agency's safety concerns with their new anti-anginal drug Raxena.[147] The court concluded that the complaint stated a claim for relief because it contained "many particularized allegations of defendants' representations of [new anti-anginal drug] Raxena's safety and efficacy, despite their knowledge of the FDA's specific and serious reservations."[148]

And in *Immune Response*, the district court denied a motion to dismiss allegations that the defendant pharmaceutical company and its executives misled

[145] 2008 WL 3842938, at *1.
[146] *Id.* at *7–8.
[147] 2004 WL 1753241, at *9.
[148] *Id.*

investors about the prospects for FDA approval of their HIV drug by withholding and misrepresenting the negative results of certain clinical studies.[149] The court carefully elucidated the basis for liability:

> All investing is based to some degree on investors' perceptions about the future. Plaintiffs presumably bought IRC securities based on their perception of whether REMUNE would have a positive effect on treating HIV and/or be approved by the FDA. . . . Plaintiffs allege that Defendants' misstatements of fact formed a false basis for its investors' perceptions. . . Where negative clinical study results are fully available to the market, investors can better weigh positive predictions [about FDA approval], and securities are more accurately valued. If, as Plaintiffs allege, Study 806 and its sub-study had shown that REMUNE had no positive effect on secondary markers, then such information would "have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[150]

As explained below, the district court dismissed Plaintiff's complaint for failure to adequately allege scienter because it fundamentally misunderstood this well-established theory of securities fraud.

B. The District Court Mistakenly Viewed This Case as a Dispute Over Defendants' Subjective Beliefs About Lorcaserin's Safety.

The district court believed that Plaintiff was urging it to infer scienter solely from the fact that the Follow Up Tests did not support the Prolactin Hypothesis.[151]

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[149] 375 F. Supp. 2d at 1023.

[150] *Id.* at 1021 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)).

[151] ER-3–5; ER-16 (footnote 9) (granting leave to amend Second Amended Complaint with instruction to limit it to "statements that support Plaintiff's theory that Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism").

It thus looked in the Second and Proposed Third Amended Complaints only for evidence that Defendants did not honestly or legitimately believe that lorcaserin was safe for humans based on the Follow Up Tests.[152] The district court also took note of the FDA's eventual approval of lorcaserin as evidence that Defendants lacked scienter because they were right.[153]

But Plaintiff's theory of fraud is not that Defendants intentionally misled the market about the objective safety of lorcaserin. Rather, Plaintiff's theory of fraud is that Defendants intentionally withheld information material to the market's assessment of whether and when the FDA would likely approve lorcaserin. That distinction is critical because a drug, regardless of its actual safety, cannot be sold until the FDA believes it is safe. Thus the FDA's *later* approval of lorcaserin, which the district court thought significant, is irrelevant.

The district court's reliance on *In re AstraZeneca, Inc. Securities Litigation*,[154] further illustrates its confusion. The district court cited *AstraZeneca* for the proposition that "a legitimate scientific disagreement alone does not give rise to a strong inference of scienter."[155] To be sure: in *AstraZeneca*, plaintiffs alleged that defendants' drug "Exanta was not as safe or as effective as defendants' public

[152] ER-6–7.
[153] ER-14–15.
[154] 559 F. Supp. 2d 453 (S.D.N.Y. 2008).
[155] ER-6.

statements made it out to be . . . ."[156] But, in that case, defendants had specifically disclosed the existence of the negative side effects that ultimately led to FDA rejection.[157] The district court in *AstraZeneca* concluded that defendants' characterization of these effects as manageable was not made with scienter simply because the FDA disagreed.[158]

Here, Defendants withheld *the very existence of their scientific disagreement with the FDA*, as well as the data that gave rise to it. As the *Immune Response* court explained, Defendants committed securities fraud by intentionally depriving investors of the opportunity to evaluate for themselves the significance of that long-running dispute.[159]

II. Plaintiff Alleged Facts Giving Rise to a Strong Inference of Scienter in the Second and Proposed Third Amended Complaints.

The district court erred in holding that the Second and Proposed Third Amended Complaints fail to adequately allege scienter under the heightened pleading requirement of the PSLRA. In *Tellabs*, the Supreme Court explained the relevant inquiry: "The reviewing court must ask: When the allegations are accepted

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[156] 559 F. Supp. 2d at 457.

[157] *See id.* at 458.

[158] *Id.* at 470.

[159] Indeed, the district court in *Immune Response* considered and rejected defendants' argument that they could not be held liable for failing to disclose "data that was not considered fatal by various scientists, or was otherwise subject to scientific dispute . . . ." 375 F. Supp. 2d at 1021.

as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?"[160] Where the inference of scienter is equally likely as any innocent explanation, the tie goes to the plaintiff.[161]

As this Court has explained, "the ultimate question [of scienter] is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity."[162] Conscious recklessness is:

> A highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.[163]

Here, the district court found "that Defendants knew the content and Arena's analysis of [the Initial Results and the results of the Follow Up Tests], as well as communications with the FDA concerning the Rat Study."[164] To be clear: there is no question about knowledge of the withheld information, the usual focus of the scienter inquiry. Indeed, under this Court's interpretation of the PSLRA, the district

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[160] 551 U.S. at 326.

[161] *Sloman v. Presstek, Inc.*, No. 06 Civ. 377, 2007 WL 2740047, at *7 (D.N.H. Sept. 18, 2007).

[162] *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010).

[163] *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 976 (9th Cir. 1999). *See also In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010) ("[A]n actor is [deliberately] reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort.").

[164] ER-3.

court's finding that Defendants had actual knowledge of material information that made their statements false should have ended the scienter inquiry.[165]

Even if Plaintiff must plead *more* than knowledge, materiality, and falsity to satisfy the PSLRA, however, he easily satisfies that additional burden. Only by failing to read the Second Amended Complaint "holistically in the light most favorable to the plaintiffs" did the district court conclude otherwise.[166] The district court ignored the obvious materiality of Defendants' misstatements and omissions as well as overwhelming circumstantial evidence that Defendants' conduct at least constituted "an extreme departure from the standards of ordinary care."[167]

A. Defendants' Multi-Year Pattern of Selective Disclosure Gives Rise to a Strong Inference of Scienter.

Defendants' pattern of disclosing the favorable results of BLOOM and BLOSSOM and linking them to the prospects for regulatory approval while failing to disclose the negative results of the Rat Study or the FDA's concerns about their relevance to humans strongly suggests scienter. An inference of scienter arises where defendants "affirmatively create[] an 'impression of a state of affairs that

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[165] *See, e.g.*, *South Ferry*, 542 F.3d at 784–86 ("Allegations [regarding management's role in a company] may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information, as in *Daou* and *Oracle*.").

[166] *Tellabs*, 551 U.S. at 326.

[167] *Silicon Graphics*, 183 F.3d at 976.

differ[s] in a material way from the one that actually exist[s].”[168] Here, Defendants created a false impression through their “incomplete [disclosures], thus portraying the results of the [lorcaserin] trial[s] in an unduly optimistic light.” [169]

Plaintiff does not contend that Defendants were under a generalized duty to disclose the results of the Rat Study, or that their failure to do so is evidence *per se* of scienter. Rather, Plaintiff alleges that having chosen to speak about the status of the lorcaserin studies, and having linked those comments to regulatory approval, Defendants assumed a duty not to mislead.[170] Defendants’ consistency in disclosing the good and withholding the bad demonstrates that they not only violated this duty, but that they did so on purpose to mislead investors.

As discussed in detail above, Arena conducted the BLOOM and BLOSSOM late-stage clinical trials at the same time as the Rat Study.[171] While Defendants quickly and specifically announced all results favorable to the prospects for

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[168] *Reese v. Malone*, 747 F.3d 557, 570 (9th Cir. 2014) (quoting *Berson*, 527 F.3d at 985).

[169] *Immune Response*, 375 F. Supp. 2d at 1022 (finding strong inference of scienter based on incomplete disclosure of clinical study results).

[170] *See, e.g.*, *Berson*, 527 F.3d at 987 (“Once defendants chose to tout the company’s backlog, they were bound to do so in a manner that wouldn’t mislead investors as to what backlog consisted of.”); *In re Elan Corp. Sec. Litig.*, 553 F. Supp. 2d 187, 208 (S.D.N.Y. 2008) (“By choosing to speak about the safety of [their drug], Defendants assumed a duty to disclose material information regarding adverse events.”) (cited in *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir. 2009)).

[171] ER-121 (SAC ¶ 64).

regulatory approval, they withheld all information tending to presage a delay or denial of the Lorcaserin Application.

To take just one example, on the May 11, 2009 conference call (the first call for investors after the BLOOM results had been compiled),[172] Defendant Lief represented, "Based on results from the BLOOM trial . . . *we believe that lorcaserin is approvable for weight management*, both here in the US, and eventually in Europe as well."[173] Defendant Lief went on to describe BLOOM's results (and the significance of those results) in detail,[174] and over the next year, Defendants released four additional press releases touting BLOOM's success.[175] Not once during this period did Defendants mention the negative results of the Rat Study or the FDA's expressed concerns—even though Defendants had submitted the final Rat Study report at the FDA's request earlier that year.

In sum, by choosing to speak about the results of the late-stage testing and the likelihood that the FDA would approve lorcaserin based on those results, "Defendants assumed a duty to disclose material information regarding adverse

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[172] ER-139 (SAC ¶ 144) (quoting ER-387–88) (March 12, 2009 call); ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call).

[173] ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call) (emphasis added).

[174] ER-145 (SAC ¶ 166) (quoting ER-250) (May 11, 2009 call).

[175] ER-146 (SAC ¶ 168); ER-148–49 (SAC ¶ 182) (quoting ER-253) (September 18, 2009 press release); ER-155 (SAC ¶ 209) (quoting ER-231) (December 22, 2009 press release); ER-155 (SAC ¶ 211) (quoting ER-288) (February 24, 2010 press release).

events."[176] The facts strongly suggest that they knowingly violated that duty here. Yet the district court completely discounted Defendants' positive statements about BLOOM and BLOSSOM, and even counseled Plaintiff to remove them from the Third Amended Complaint altogether.[177]

B. Defendants' Multi-Year Pattern of Material Misstatements Gives Rise to a Strong Inference of Scienter.

Defendants did not merely selectively disclose the good and withhold the bad; they affirmatively misrepresented the former and hid the latter. "One of the classic fact patterns giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to information suggesting that their public statements were materially inaccurate."[178] And as this Court has explained, under these circumstances "falsity and scienter are generally inferred from the same set of facts."[179]

As described in detail above, in the nineteen months between the conclusion of the Rat Study and the rejection of the Lorcaserin Application, Defendants

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[176] *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1324 (2011); *Elan Corp.*, 553 F. Supp. 2d at 208 (cited in *Siracusano*, 585 F.3d at 1181).

[177] ER-19 (footnote 13).

[178] *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 646, 665 (8th Cir. 2001).

[179] *In re Read-Rite Corp.*, 335 F.3d 843, 845 (9th Cir. 2003); *see also Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001); *Nursing Home Pension Fund, Local 144 v. Oracle Corp.* 380 F.3d 1226, 1230 (9th Cir. 2004).

consistently represented to the public that the data on lorcaserin was uniformly positive.[180] For example, in March 2009, Defendants Lief and Shanahan each independently cited lorcaserin's animal studies as a *positive* factor favoring FDA approval. Defendant Lief offered that "*confidence* [in lorcaserin's FDA approval was] based on the Phase II data, the Phase I data, the preclinical studies that was done, *all the animal studies that have been completed* . . . .",[181] and Defendant Shanahan claimed that "[a]nimal studies" provided "a lot of visibility on our safety associated with lorcaserin."[182] Defendant Anderson later went so far as to say that "we have favorable results on *everything* that we've compiled so far."[183]

Like Defendants' public statements, the language in the SEC filings was calculated to create an unduly favorable investor impression of the prospects for quick approval of the Lorcaserin Application. For example, Arena's first 10-Q after completing the Rat Study contained some generalized warnings about the possibility that a drug in development may not be approved,[184] but also specifically represented:

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[180] *See supra* pages 12–18 (Statement of the Case Section II.C).

[181] ER-144 (SAC ¶ 160) (quoting ER-315) (March 31, 2009 press release).

[182] ER-140 (SAC ¶ 146).

[183] ER-151 (SAC ¶ 190) (quoting ER-263) (September 18, 2009 call) (emphasis added).

[184] The district court held in a footnote that these boilerplate disclosures "sufficiently warned investors of potential risk regarding scientific data interpretation. . . ." ER-5 (footnote 3). But such generic disclosures are inadequate when a more specific risk has already materialized. As one district court vividly put it, "The doctrine of bespeaks caution provides no protection to someone who warns

"To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our drug candidates, except lorcaserin."[185] That statement repeats in every 10-Q and 10-K until the FDA Advisory Committed voted to recommend not approving the Lorcaserin Application in September 2010.[186]

In contrast, less than a month *after* the FDA rejected the Lorcaserin Application, Arena finally disclosed the longstanding material risks of FDA denial or delay:

> We conducted long-term carcinogenicity preclinical studies of lorcaserin. The FDA identified [] lorcaserin issues related to such studies. We intend to provide in our response to [the FDA] data and other information to support our view related to such issues, *but the FDA may disagree with our view or impose conditions that could delay or preclude approval of our lorcaserin [Application]*.[187]

Defendants knew how to accurately communicate the risk of regulatory delay or denial associated with the negative results from the Rat Study. They simply chose

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his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away." *In re Prudential Secs. Inc. P'ships Litig.*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996). Here, Defendants knew that there were specific results of a required nonclinical study that concerned the FDA, but Defendants at best warned of a hypothetical risk.

[185] ER-140–41 (SAC ¶ 148) (quoting ER-205, 209) (Annual Fiscal Year 2008 Form 10-K).

[186] ER-209 (Annual Fiscal Year 2008 Form 10-K); ER-228 (Annual Fiscal Year 2009 Form 10-K); ER-359 (Third Quarter 2009 Form 10-Q); ER-410 (First Quarter 2009 Form 10-Q); ER-422 (Second Quarter 2009 Form 10-Q); ER-432 (Third Quarter 2009 Form 10-Q); ER-443 (First Quarter 2009 Form 10-Q); ER-458 (First Quarter 2010 Form 10-Q); ER-476 (Second Quarter 2010 Form 10-Q).

[187] ER-105 (November 9, 2009 press release) (emphasis added).

to withhold that information until after they had raised sufficient capital to remain in business throughout a more prolonged regulatory process.

In concluding that Defendants lacked scienter, the district court necessarily determined that the pre-September 2010 above statements *were not false*. For example, the order dismissing the First Amended Complaint stated that it was "more plausible that [Defendants] . . . reasonably believed the results [of the Rat Study] to be positive with regard to what the study was designed to test" whether lorcaserin causes cancer in humans—than that they recklessly disregarded the falsity of their statements.[188] The November 4 Order similarly concluded that Defendant Lief's statement that "confidence is based on . . . all the animal studies that have been completed" was not reckless because he believed lorcaserin's overall safety profile and potential to be "positive, favorable, or encouraging."[189]

That determination is both wrong and inappropriate at this stage of the proceedings. First, these statements were clearly false. Even if Defendants felt that the Follow Up Tests *mitigated* the highly unfavorable initial results of the Rat Study, no reasonable person would understand or describe the animal studies as "favorable" or inspiring "confidence."[190] And even if Defendants reasonably believed lorcaserin

[188] ER-30.
[189] ER-14–15.
[190] In addition to those clearly false and misleading statements, Defendants made numerous other general statements about the lack of safety concerns for lorcaserin.

to be completely safe, that belief would not be *based on* "all the animal studies that have been completed." More to the point, a motion to dismiss is not the appropriate vehicle for making a factual determination about falsity.[191] "[O]nly if 'reasonable minds' could not disagree that the challenged statements were misleading should the district court dismiss under 12(b)(6)."[192]

C. Defendants' Actions Evidencing Their Doubts about Seamless FDA Approval Give Rise to a Strong Inference of Scienter.

Scienter may be pled and proven by reference to circumstantial evidence of a company's activities.[193] In evaluating that evidence, the reviewing court considers "whether the total of plaintiff's allegations, even though individually lacking, are sufficient to create a strong inference that defendants acted with deliberate or conscious recklessness."[194] Any suspicious behavior may contribute to that inference. For example, "'[u]nusual trading or trading at suspicious times or in suspicious amounts by corporate insiders has long been recognized as probative of

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ER-142–43 (SAC ¶ 155) (quoting ER-309, 312) (March 30, 2009 call); ER-157 (SAC ¶ 219) (quoting ER-390, 392, 393) (March 12, 2010 call); ER-161–62 (SAC ¶ 240) (quoting ER-400) (August 3, 2010 call).

[191] *Immune Response*, 375 F. Supp. 2d at 1021 ("At a later stage, the issue of the reasonableness of Defendants' belief in their statements may be more appropriately raised. At this stage, however, it is simply not within the Court's authority to make such determinations.").

[192] *Warshaw*, 74 F.3d at 959.

[193] *See, e.g.*, *Connetics*, 2008 WL 3842938, at *3; *CV Therapeutics, Inc.*, 2004 WL 1753241, at *3.

[194] *Nursing Home*, 380 F.3d at 1230.

scienter.'"[195] While evidence of a specific fraudulent motive is not required, it is often persuasive.[196]

In January 2009 or shortly before, Arena completed the supplemental portion of the Rat Study designed to demonstrate to the FDA that lorcaserin's carcinogenic mechanism does not affect humans.[197] Immediately following the conclusion of the Follow Up Tests, Arena reduced its expenses and rushed to procure additional capital. And before meeting with the FDA Advisory Committee, Arena retained a world-class pathologist to present and explain the results of the Follow Up Tests. In short, Arena began to behave like a company that had discovered that it might need more resources and more time to bring its only drug to market.

As described in detail above, Arena suspended all unnecessary purchases and laid off 31 percent of its workforce in early 2009—changes that Arena employees understood to be linked to uncertainty about the future of lorcaserin.[198] It reduced

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[195] *Daou*, 411 F.3d at 1022 (quoting *Greebel v. FTP Software*, 194 F.3d 185, 197 (1st Cir. 1999)).

[196] *See Tellabs*, 551 U.S. at 325 (acknowledging motive as relevant consideration in scienter analysis); *Daou*, 411 F.3d at 1024 (considering personal motive as factor in totality of circumstances); *Reese*, 747 F.3d at 572 (executive's motive supported compelling inference of scienter).

[197] The FDA was first apprised of the initial Rat Study's worrisome results on May 31, 2007, and it directed Arena to provide bi-monthly status updates on the Follow Up Tests going forward. ER-112 (SAC ¶ 15). The FDA received at least ten total updates from Arena, so the last update was presumably January 2009. ER-124 (SAC ¶ 79). Arena submitted the final report on the Follow Up Tests to the FDA on February 3, 2009. ER-126 (SAC ¶ 93).

[198] *See supra* pages 18–19 (Statement of the Case Section II.D).

its total operating costs by $5 million that year after multi-million dollar operating cost increases the two previous years. At the same time, Arena issued new stock to the public at a frantic pace, raising over $150 million between April 2009 and June 2010, compared to under $2 million issued in 2008. On July 6, 2009, Arena secured a $100 million four-year loan with a balloon payment of $40 million plus interest.

From Defendants' perspective, these measures would be necessary for the Company to remain solvent for two more years if the Lorcaserin Application was not approved in 2010. Arena's cash-raising efforts gave them an extra $190 million of liquidity: $150 million in new stock plus the $40 million portion of the loan that came due in late 2013. That $190 million amount is *precisely* what Arena might have forecasted needing to withstand a two-year delay in the approval of the Lorcaserin Application. In fact, from the fourth quarter of 2010 (when the Lorcaserin Application was rejected) through lorcaserin's eventual approval in 2012, Arena's operating expenses were slightly over $190 million.[199]

Taken as a whole, the circumstantial evidence supports a compelling inference that Defendants consciously misled the market about material information to ensure that Arena remained solvent pending eventual FDA approval of lorcaserin. This motive differs from the commonplace corporate interest in bolstering stock price

[199] *See generally* Arena's First, Second, and Third Quarter 2012 Form 10-Qs, and Annual Fiscal Year 2012 Form 10-K, available at http://www.sec.gov/edgar.shtml.

because Defendants took specific and uncharacteristic actions to further their specific goal of remaining solvent through 2012.[200] Not only did they issue more than 75 times as much stock in a fourteen-month period from 2009 to 2010 as they issued in 2008, but they slashed operating expenses after years of multi-million dollar increases.

Although the district court purported to read the Second and Proposed Third Amended Complaints "holistically in the light most favorable to the plaintiffs," it instead dismissed this circumstantial evidence altogether. The district court acknowledged that it found the confidential informant testimony unpersuasive, and it considered the remaining evidence irrelevant to Defendants' state of mind with respect to the *safety* of lorcaserin.[201] The district court did not even mention Defendants' retention of a consultant to review their drug, which itself, supports the "cogent and compelling" inference that Defendants elected not to disclose the results

[200] In addition, many of Arena's stock sales were suspiciously timed to coincide with Defendants' misrepresentations. For example, Arena sold $60 million in stock on August 6, 2010, just two days after Defendant Shanahan told investors that there would be no surprises at the September 2010 meeting with the FDA Advisory Committee. ER-120 (SAC ¶ 60). The sale was thus "calculated to maximize [the benefit to Arena] from undisclosed inside information." *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989).

[201] ER-15 (footnote 8).

of the Rat Study "not because [they] believed they were meaningless but because [they] understood their likely effect on the market." [202]

III. The District Court's Scienter Holding Is Unworkable.

If this Court approves the district court's application of the pleading requirement for scienter in this case, then no securities class action lawsuit in the Ninth Circuit will survive a motion to dismiss absent "smoking gun" evidence.[203] That is manifestly not what Congress intended in enacting the PSLRA, and it is contrary to Supreme Court precedent.

A. Plaintiff Has Assembled an Overwhelming Circumstantial Case of Fraud Without the Benefit of Formal Discovery.

In this case, Plaintiff alleged in painstaking detail that Defendants knowingly made specific representations and omissions that misled the market about the likelihood and timing of FDA approval of lorcaserin. When investors learned of the information that Arena had misrepresented and withheld, the price of Arena stock fell 40 percent in one day. Plaintiff has further alleged circumstances suggesting that Defendants defrauded investors to further their project of funding Arena's operations through eventual FDA approval.

It bears emphasis that although this litigation is now nearly four years old, it has yet to transcend the pleading stage. There is still no "evidence" before the Court,

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[202] *Matrixx Initiatives*, 131 S. Ct. at 1324–25.
[203] *Cf. Tellabs*, 551 U.S. at 324.

only factual allegations and inferences. Yet to decide the very preliminary question of whether Plaintiff has alleged sufficient facts *to warrant the discovery and introduction of evidence* in support of his claim,[204] the district court has considered over 1100 pages of documentary material, considered over 375 pages of briefing on the merits, and conducted nearly 2 hours of oral argument. Plaintiff might well prevail in his action on the strength of the existing record alone—surely a sign that something is amiss.[205]

The persuasiveness of the record as it stands is especially remarkable because, as is usually true of this type of litigation, most of the relevant evidence remains in Defendants' exclusive possession. Tellingly, Defendants attempted to introduce nine selected pages of the Lorcaserin Application for the district court's consideration without producing the remaining pages to Plaintiff.[206] Without access even to the Lorcaserin Application itself, Plaintiff has assembled an overwhelming circumstantial case of fraud.

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[204] *See Scheuer*, 416 U.S. at 236.

[205] *See, e.g.*, *In re Network Equip. Techs., Inc. Litig.*, 762 F.Supp. 1359, 1368 (N.D. Cal. 1991) ("Court[s] should not . . . generate an evidentiary record and then weigh evidence . . . to dismiss [a] complaint."); *In re Northpoint Comms. Grp., Inc.*, 221 F. Supp. 2d 1090, 1095 (N.D. Cal. 2002) (consideration of exhibits encourages improper weighing of factual disputes); *Levenstein v. Salafsky*, 164 F.3d 345, 347 (7th Cir. 1998) (judicial notice at pleading stage a "narrow exception" and not license to eliminate distinction between summary judgment and motion to dismiss).

[206] ER-4 (footnote 2).

B. If Plaintiff's Allegations Do Not Suffice Here, Then Sophisticated Fraudsters May Act With Impunity.

If Plaintiff's allegations here do not meet the scienter standard, then it is necessary for defrauded investors to produce direct evidence of what companies and their executives were actually thinking merely *to survive the pleading stage.*[207] Of course, such evidence will hardly ever be available before formal discovery, especially in the overwhelming majority of cases in which the key actors are sophisticated. And if a company and its representatives do not act with "scienter" whenever the substance of their statements or omissions might reasonably be deemed scientific, technical, or otherwise open to "legitimate disagreement" about its significance, then they are exempt from the disclosure laws altogether.

In practice, the upshot of the district court's interpretation and application of the PSLRA scienter requirement would be to deprive most defrauded purchasers and sellers of securities of any private remedy whatsoever. That is not what Congress intended when it enacted the PSLRA to restore private securities litigation as "an indispensable tool with which defrauded investors can recover their losses without

[207] In theory, there might be exception for the exceedingly rare case in which a misrepresentation admits of no conceivable non-fraudulent explanation. *See South Ferry*, 542 F.3d at 786 (citing *Berson*, 527 F.3d at 988). Of course, the Supreme Court in *Tellabs* made clear that to survive the pleading stage, the inference of scienter need not even be "the 'most plausible of competing inferences,'" but merely "at least as compelling as any opposing inference once could draw from the facts alleged." 551 U.S. at 324.

having to rely upon government action."[208] It is also expressly contrary to the Supreme Court's admonition that the "strong inference" of scienter standard must be applied in a way that "preserv[es] investors' ability to recover on meritorious claims"[209] by "allow[ing] meritorious actions to go forward."[210]

CONCLUSION

The district court's November 4 Order dismissing the Second Amended Complaint should be reversed. Alternatively, the district court's March 20 Order denying Plaintiff's motion for leave to amend should be reversed.

Dated: August 27, 2014

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[208] H.R. REP. NO. 104-369, at 31.
[209] *Tellabs,* 551 U.S. at 322.
[210] *Id.* at 324.

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STATEMENT OF RELATED CASES

There are no known related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I certify that:

1. The brief complies with the length limits set forth at Fed. R. App. P. 32(a)(7)(B) because it has 14,000 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6) because the brief is proportionately spaced using 14-point Times New Roman type.

Dated: August 27, 2014

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CERTIFICATE OF SERVICE

I hereby certify that, on August 27, 2014, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that some of the participants in the case are not registered CM/ECF users. Upon acceptance by the Clerk of the Court of the electronically filed document, one copy of the foregoing will be served, via U.S. Mail, postage prepaid on:

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Dated: August 27, 2014

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